Proposed Registration Decision PRD2010-13

# Beauveria bassiana strain HF23

*(publié aussi en français)*

**1 June 2010**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

HC Pub: 100270

ISBN: 978-1-100-16003-0 978-1-100-16004-7
Catalogue number: H113-9/2010-13E H113-9/2010-13E-PDF

**© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2010**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

# Table of Contents


Overview ..... 1
Proposed Registration Decision for *Beauveria bassiana* strain HF23 ..... 1
What Does Health Canada Consider When Making a Registration Decision? ..... 1
What Is *Beauveria bassiana* strain HF 23? ..... 2
Health Considerations ..... 3
Environmental Considerations ..... 4
Value Considerations ..... 5
Measures to Minimize Risk ..... 5
Next Steps ..... 5
Other Information ..... 6
Science Evaluation ..... 7
1.0 The Active Substance, Its Properties And Uses ..... 7
1.1 Identity of the Active Ingredient ..... 7
1.2 Physical and Chemical Properties of the Active Substances and End-use Product ..... 8
1.3 Directions for Use ..... 9
1.4 Mode of Action ..... 9
2.0 Methods Of Analysis ..... 9
2.1 Methods for Identification of the Microorganism ..... 9
2.2 Methods for Establishment of Purity of Seed Stock ..... 9
2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products ..... 9
2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites ..... 10
2.5 Methods for Determination of Relevant Impurities in the Manufactured Material ..... 10
2.6 Methods to Show Absence of Any Human and Mammalian Pathogens ..... 10
2.7 Methods to Determine Storage Stability, Shelf-life of the Microorganism ..... 10
3.0 Impact on Human and Animal Health ..... 10
4.0 Impact on the Environment ..... 10
5.0 Value ..... 11
6.0 Pest Control Product Policy Considerations ..... 11
6.1 Toxic Substances Management Policy Considerations ..... 11
6.2 Formulants and Contaminants of Health or Environmental Concern ..... 11
7.0 Summary ..... 12
7.1 Methods for Analysis of the Micro-organism as Manufactured ..... 12
7.2 Human Health and Safety ..... 12
7.3 Environmental Risk ..... 13
7.4 Value ..... 13
8.0 Proposed Regulatory Decision ..... 14
List of Abbreviations ..... 15
References ..... 17

# Overview

## Proposed Registration Decision for *Beauveria bassiana* strain HF23

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of *Beauveria bassiana* HF 23 Technical and Balence ES containing the technical grade active ingredient *Beauveria bassiana* strain HF23 to control house flies in poultry production houses.

*Beauveria bassiana* HF 23 Technical (Registration Number 28889) and Balence ES (Registration Number 28890) are conditionally registered in Canada. The detailed review for *Beauveria bassiana* HF 23 Technical and Balence ES can be found in ERC2008-04 *Beauveria bassiana HF 23*. The current applications were submitted to convert *Beauveria bassiana* HF 23 Technical and Balence ES from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of *Beauveria bassiana* HF 23 Technical and Balence ES.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on *Beauveria bassiana* strain HF 23, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on *Beauveria bassiana* strain HF 23, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

## What Is *Beauveria bassiana* strain HF 23?

*Beauveria bassiana* strain HF23 is a fungus which is used as a microbial pest control agent to control house flies in poultry production houses. This fungus causes a fatal disease in insects known as white muscardine disease. The HF23 strain of *B. bassiana* was originally isolated from a house fly in the USA and is reported to be quite specific to house flies and related flies associated with livestock facilities.

The end-use product, Balence ES, is a commercial class insecticide product that contains *B. bassiana* strain HF23 as the active ingredient. While application in poultry production houses may be considered an indoor use, the chicken manure exposed to the application of Balence ES inside the poultry production house is commonly rendered into fertilizer and used outdoors on agricultural crops. Therefore, this outdoor use was also considered in the human health and the environmental risk assessment.

---

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

## Health Considerations

### Can Approved Uses of *Beauveria bassiana* strain HF23 Affect Human Health?

**_Beauveria bassiana_ strain HF23 is unlikely to affect your health when Balence ES is used according to label directions**

Exposure to *B. bassiana* strain HF23 may occur during handling of Balence ES. When assessing health risks, several key factors are considered: the microorganism's biological properties (e.g., production of toxic by-products); reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies; and the likely levels to which people may be exposed relative to exposures already encountered in nature to other strains of the microorganism. Toxicology studies in laboratory animals describe potential health effects from large doses for the purpose of identifying any potential to cause disease or toxicity. There were no signs that *B. bassiana* strain HF23 caused any significant toxicity or disease when tested on laboratory animals.

**Residues in Water and Food**

**Dietary risks from food and water are not of concern**

The Food and Drugs Act prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the Pest Control Products Act. Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Although Balence ES is intended for use in an indoor environment (i.e., on chicken manure in poultry houses), treated chicken manure is to be rendered into fertilizer and used outdoors on agricultural crops. This agricultural use pattern is the only means for potential residues of the active ingredient to arise on food/feed items. Based on the natural occurrence of *B. bassiana* in cultivated soils, and on the limited and indirect agricultural use of treated manure, it is not expected that the use of Balence ES will significantly increase the natural environmental background levels of this microorganism.

As there are no direct applications to food and as no significant adverse effects were reported in Tier I acute toxicity/pathogenicity studies, the establishment of a maximum residue limit (MRL) is not required for *B. bassiana* strain HF23. As well, the likelihood of residues contaminating drinking water supplies is negligible. Consequently, dietary exposure and risk are minimal to non-existent

### Occupational Risks From Handling Balence ES

**Occupational risks are not of concern when Balence ES is used according to label directions, which include protective measures**

Workers using Balence ES can come into direct contact with *B. bassiana* strain HF23 on the skin, in the eyes, or by inhalation. For this reason, the label will specify that users exposed to Balence ES must wear waterproof gloves, a long-sleeved shirt, long pants, shoes plus socks and a NIOSH approved respirator/mask with any N-95, P-95, R-95 or HE filter. For bystanders, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

## Environmental Considerations

### What Happens When *Beauveria bassiana* strain HF23 Is Introduced Into the Environment?

**Environmental risks are not of concern**

Although Balence ES is intended for use in an indoor environment (i.e., in poultry production houses), chicken manure exposed to the application of Balence ES in the poultry production house may be rendered into fertilizer and used outdoors on agricultural crops. Studies designed to examine the environmental fate of *B. bassiana* strain HF23 were assessed. *B. bassiana* strain HF23 does not remain viable in chicken manure and chicken litter for long periods of time and is unable to grow at temperatures above 35°C. Application to manure and subsequent composting of the manure is expected to significantly reduce the level of viable cells or spores of *B. bassiana* strain HF23 released into the environment.

The effects of *B. bassiana* strain HF23 on birds was examined. No significant adverse effects were observed in birds when *B. bassiana* strain HF23 was administered orally. Rationales were reviewed to waive avian pulmonary/inhalation/injection, wild mammal, freshwater fish, terrestrial arthropod (including honeybee), aquatic arthropod, non-arthropod invertebrate, and plant testing. The rationales were considered acceptable and significant adverse effects to these non-target organisms are not expected.

## Value Considerations

### What Is the Value of Balence ES?

*Beauveria bassiana* strain HF23, formulated as the end-use product Balence ES, has value in controlling populations of house flies in poultry production houses.

Application of Balence ES to various surfaces in poultry production houses can control populations of house flies by infecting and killing the adult flies. *B. bassiana* strain HF23 provides an alternative to conventional chemical insecticides and is well-suited for incorporation into integrated pest management programs.

## Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Balance ES to address the potential risks identified in this assessment are as follows.

### Key Risk-Reduction Measures

### Human Health

Because of concerns with dermal irritation and with users developing allergic reactions through repeated high exposures to *B. bassiana* strain HF23, anyone handling Balence ES must wear waterproof gloves, a long-sleeved shirt, long pants, shoes plus socks and a NIOSH approved respirator/mask with any N-95, P-95, R-95 or HE filter.

## Next Steps

Before making a final registration decision on *Beauveria bassiana* strain HF23, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

## Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on *Beauveria bassiana* strain HF23 (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

# Science Evaluation

## *Beauveria bassiana* strain HF 23

## 1.0 The Active Substance, Its Properties And Uses

### 1.1 Identity of the Active Ingredient

| | |
|---|---|
| **Active microorganism** | *Beauveria bassiana* strain HF23 |
| **Function** | Control houseflies poultry production houses |
| **Binomial name** | *Beauveria bassiana* strain HF23 |
| **Taxonomic designation** | |
| **Kingdom** | Eumycota |
| **Phylum** | Dikarymycota |
| **Subphylum** | Ascomycotina |
| **Class** | Pezizomycotina |
| **SubClass** | Sordariomycete |
| **Order** | Hypocreales |
| **Family** | Clavicipitaceae |
| **Genus** | *Beauveria* |
| **Species** | *Bassiana* |
| **Strain** | HF23 |
| **Patent Status information** | No Canadian patent status information was provided. |
| **Minimum purity of active** | $4.75 \times 10^{11}$ colony forming units (CFU)/g |
| **Identity of relevant impurities of toxicological, environmental and/or significance.** | The technical grade active ingredient does not contain any impurities or microcontaminants known to be TSMP Track 1 substances. Beauvericin, a secondary metabolite of *B. bassiana* strain HF23 has been identified in the technical product. Each lot of techical product will be monitored to ensure that beauvericin is at acceptable levels.<br>Although it does not appear on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern (Canada Gazette part II, Volume 139, Number 24, pages 2641-2643), a component of one of the formulants in Balence ES is considered to be toxic as defined in Section 64 of the Canadian Environmental Protection Act, 1999 (CEPA, 1999). PMRA has conducted a risk assessment of this formulant component and has found that the associated risk is acceptable for the proposed use. |

## 1.2 Physical and Chemical Properties of the Active Substances and End-use Product

**Technical Product—*Beauveria bassiana* HF23 Technical**

| Property | Result |
|---|---|
| Colour | white to light beige |
| Odour | slight must smell |
| Physical state | Powder |
| Guarantee | $4.75 \times 10^{11}$ CFU/g |
| Density | 0.181 g/cm$^3$ |
| Storage stability | N/A |
| Flammability | N/A |
| Explodability | Non-explosive |

N/A = not applicable

**End Use Product—Balence ES**

| Property | Result |
|---|---|
| Colour | dark amber |
| Odour | citrus |
| Physical state | liquid |
| Formulation type | emulsifiable suspension |
| Guarantee | 1.18% *B. bassiana* strain HF23<br>minimum of $5.6 \times 10^9$ CFU/g |
| Specific gravity | 0.92 g/cm$^3$ |
| Storage stability | 14 months when stored at 22~26°C |
| Corrosion characteristics | Non-corrosive |
| Flammability | N/A |
| Explodability | N/A |

N/A = not applicable

### 1.3 Directions for Use

Application rate of the end-use product Balence ES is 9.5 to 16 mL per 100 m2. Apply the spray to walls, floors, posts and manure concentrating areas where the greatest numbers of pests are located. This is a contact infection material with greatest efficacy against adult flies. Re-treat at intervals of 2 to 7 days as long as pest pressure persists as pest eggs hatch and mature. There is no restriction on the total maximum amount of product that may be applied in a year.

### 1.4 Mode of Action

*Beauveria bassiana* is a generalist entomopathogenic fungus that causes white muscardine disease, which is lethal to insects. When spores of the fungus come into contact with an insect host, the spores germinate and hyphae grow into the body of the insect, eventually killing it. After death of the host, a white mycelium grows over the body of the host and produces new fungal spores. The HF23 strain of *B. bassiana* originally was isolated from a house fly in the USA and is reported to be quite specific to house flies and related flies associated with livestock facilities.

## 2.0 Methods Of Analysis

### 2.1 Methods for Identification of the Microorganism

*Beauveria bassiana* strain HF23 is a Hyphomycete fungus, producing conidia on exposed conidiophores. The genus *Beauveria* is closely related to the genera *Tritirachium* and *Acrodontium*. *Beauveria bassiana* strain HF23 can be identified to the species level by microscopic examination of morphological features, such as conidial production and ramification, by the method of deHoog (1972).

*Beauveria bassiana* strain HF23 can be distinguished from naturally occurring strains of *B. bassiana* by vegetative compatibility group (VCG) analysis.

### 2.2 Methods for Establishment of Purity of Seed Stock

Please refer to ERC2008-04 Section 2.2 for more information on the methods for establishment of purity of seed stock.

### 2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products

Please refer to ERC2008-04 Section 2.3 for more information on the methods to define the content of the microorganism in the manufactured material used for the production of Balance ES.

### 2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites

Please refer to ERC2008-04 Section 2.4 for more information on the methods to determine and quantify residues (viable or non-viable) of the active microorganism and relevant metabolites.

### 2.5 Methods for Determination of Relevant Impurities in the Manufactured Material

The quality control (QC) procedures used to limit contaminating microorganisms during manufacture of Balence ES are acceptable. The technical product is checked for purity by microscopic examination, as well as by agar plate counts on non-specific growth media following standard methods to detect any unusual colonies, and to verify colony morphology. In the event that the microbial contaminants in a batch exceed the acceptable limits, the contaminated lot is removed from the production run.

The manufacturing process is conducted under aseptic conditions, with the use of filtered air and water and food-grade quality ingredients only to minimize the potential for contamination by extraneous microorganisms. Airborne contamination is also monitored during the manufacturing process. Representative batch data on the EP confirmed that contamination was limited largely to innocuous environmental microorganisms.

While the registrant did not provide contaminant screening data specific for human pathogens, the Agency is confident that the QC measures utilized will minimize the potential for contamination of the end use product, Balence ES.

### 2.6 Methods to Show Absence of Any Human and Mammalian Pathogens

As noted in section 2.5, while the registrant did not provide contaminant screening data specific for human pathogens, the Agency is confident that the QC measures utilized will minimize the potential for contamination of the end use product, Balence ES.

### 2.7 Methods to Determine Storage Stability, Shelf-life of the Microorganism

Please refer to ERC2008-04 Section 2.7 for more information on the methods to determine storage stability, shelf-life of the microorganism.

## 3.0 Impact on Human and Animal Health

Please refer to ERC2008-04 Section 3.0 for a detailed summary of the toxicological, occupational exposure and the food residue exposure assessment.

## 4.0 Impact on the Environment

Please refer to ERC2008-04 Section 4.0 for a detailed summary of the environmental fate and environmental toxicological assessment.

## 5.0 Value

Please refer to ERC2008-04 Section 5.0 for a detailed summary of the value assessment.

## 6.0 Pest Control Product Policy Considerations

### 6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

While reviewing *Beauveria bassiana* strain HF23, the PMRA took into account the federal Toxic Substances Management Policy and followed its Regulatory Directive DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy. Substances associated with its use were also considered, including microcontaminants in the technical product, *Beauveria bassina* HF23 Technical and formulants in the end use product Balence ES. The PMRA has reached the following conclusions:

- *Beauveria bassiana* strain HF23 Technical does not meet the Track 1 criteria because the active ingredient is a biological organism and hence is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products. There are also no formulants, contaminants or impurities present in the end-use product that would meet the TSMP Track-1 criteria.

- Therefore, the use of *Beauveria bassiana* strain HF23 Technical is not expected to result in the entry of Track 1 substances into the environment.

### 6.2 Formulants and Contaminants of Health or Environmental Concern

The end-use product, Balence ES, contains the formulant soybean oil, which is identified in Canada Gazette Part II, Volume 139, Number 24, pages 2641-2643: *List of Pest Control Product Formulants of Health or Environmental Concern* as an allergen known to cause anaphylactic-type reactions. Therefore the label for Balence ES will include the precautionary statement: "Warning: this product contains the allergen soybean oil" on the principal display panel.

Although it does not appear on the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* (Canada Gazette, part II, Volume 139, Number 24, pages 2641B2643), a component of one of the formulants in Balence ES is considered to be toxic as defined in section 64 of the *Canadian Environmental Protection Act, 1999*. The PMRA has conducted a risk assessment of this formulant component and has found that the associated risk is acceptable for the proposed use.

## 7.0 Summary

### 7.1 Methods for Analysis of the Micro-organism as Manufactured

The product characterization data for *Beauveria bassiana* HF23 Technical and Balence ES are adequate to assess their safety to human health. The technical material was fully characterized and the specifications were supported by the analysis of a sufficient number of batches.

The quality control procedures used to limit contaminating microorganisms during manufacture of Balence ES are acceptable. Although pathogen specific screening methods are not part of the QA/QC program, given the limited use pattern and the requirement for PPE during all handling activities, as well as on the lack of food uses, and representative contaminant data from an adequate number of batches, the PMRA is reasonably assured the QA/QC program will not result in an unacceptable risk to human health or the environment.

Storage stability data were sufficient to support an expiration date of 14 months for Balence ES when the products are stored at room temperature (20-27.5°C).

### 7.2 Human Health and Safety

The acute toxicity and infectivity studies submitted in support of *B. bassiana* strain HF23 were determined to be sufficiently complete to permit a decision on registration. *B. bassiana* strain HF23 was of low toxicity in the rat when administered via the oral, pulmonary, intraperitoneal and dermal routes and was not pathogenic or infective via the oral, pulmonary and intraperitoneal routes. In the oral and pulmonary studies, clearance was established by day 3. The technical product was not found to be a dermal irritant and the end-use product was not found to be toxic via the dermal route.

Non - minimal/slight ocular irritation was observed with both the technical product and the end-use product.

The PMRA assumes that all microorganisms contain substances that can elicit positive hypersensitivity reactions. Exposure to allergens, including *B. bassiana* strain HF23 may cause allergies following repeated exposures. As a result, the signal words "POTENTIAL SENSITIZER" are required on the principal display panels of all technical and end-use products and risk mitigation measures are required to protect populations that are likely to be primarily exposed to the products. Such exposure to handlers and early-entry workers can be minimized if they wear gloves, long-sleeved shirts, long pants, NIOSH approved respirators (with any –95, P-95, R-95 or HE filter), shoes and socks.

When handled according to the label instructions, the pulmonary, dermal and ocular routes are potential routes of exposure to mixer/loaders, handlers and early-entry workers. To minimize risk to workers, use of appropriate personal protective equipment (PPE) will be stipulated on product labels. The labels do not allow application to turf, residential or recreational areas. As the use sites are agricultural, exposure to infants and children in school, residential and daycare facilities is likely to be minimal to non-existent. Consequently, the health risk to infants and children is expected to be negligible.

As there are no direct applications to food and as no significant adverse effects were reported in the Tier I acute toxicity/pathogenicity studies, the establishment of a maximum residue limit (MRL) is not required for *B. bassiana* strain HF23 under Section 4(d) of the Food and Drugs Act (adulteration of food) as defined under Division 15, Section B.15.002 of the Food and Drugs Regulations.

### 7.3 Environmental Risk

The environmental fate studies, non-target studies and waivers submitted in support of *B. bassiana* strain HF23 were determined to be sufficiently complete to permit a decision on registration.

The environmental fate studies submitted indicated that *B. bassiana* strain HF23 does not persist in chicken manure or chicken litter and has limited viability at temperatures above 35–37°C.

An acute oral toxicity in chickens concluded that *B. bassiana* strain HF23, with an $LD_{50}$ of > 0.91 g/kg bw, poses a minimal risk to birds when administered via the oral route. The remaining groups of non-target organisms including birds (pulmonary/inhalation/injection), wild mammals, terrestrial arthropods (including honeybees), non-arthropod invertebrates, terrestrial plants, freshwater fish and aquatic arthropods, were addressed through waivers. The waivers were based on the ubiquitous nature of the active ingredient, the proposed indoor uses, the limited viability of the active ingredient in light of the use, and, in some cases, literature reports or study results which indicate a lack of adverse effects.

The waivers were found to be acceptable and testing of non-target organisms was not required. As a general precaution, the label prohibits the direct application of the product to aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats. The label also directs handlers to not contaminate surface water by disposal of equipment wash waters. Furthermore, as some strains of *B. bassiana* have been shown to be toxic to honeybees, users are directed to avoid applying the product to areas where honeybees are actively foraging or around hives.

### 7.4 Value

*Beauveria bassiana* strain HF23, formulated as the end-use product Balence ES, has value in controlling populations of house flies in poultry production houses.

## 8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of *Beauveria bassiana* strain HF23 Technical and Balence ES to suppress houseflies in chicken manure and in poultry production and livestock houses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

## List of Abbreviations

| | |
|---|---|
| °C | degree(s) Celsius |
| CFU | colony forming units |
| g | gram |
| MRL | maximum residue limit |
| PCPA | Pest Control Products Act |
| PMRA | Pest Management Regulatory Agency |
| TGAI | technical grade of the active ingredient |
| TSMP | Toxic Substances Management Policy |
| QA | quality assurance |
| QC | quality control |

# References

## A. List of Studies/Information Submitted by Registrant

### 1.0 Chemistry


| PMRA NO. | Title |
|---|---|
| 1443964 | De Hoog, G.S. 1972. The genera *Beauveria*, *Isaria*, *Tritirachium* and *Acrodontium* Gen. Nov. Studies in Mycology, No. 1. Baarn, Netherlands. 15 September 1972. DACO 2.7.1. |
| 1644563 | DACOM2.7.1i Origin, derivation and identification of *Beauveria bassiana* HF23, DACO: M2.7.1 CBI |
| 1644564 | Product Specifications: Bulk Density correction and normal concentration, DACO: M2.9.1 CBI |
| 1644597 | 2008, Covering letter, DACO: 0.8 |
| 1644601 | 2008, PMRA approved label, DACO: M1.1 |
| 1644602 | 2008, DACO M2.10.2 Analysis for Microbial Contaminants, DACO: M2.10.2 CBI |
| 1644604 | 2007, Certificates of Analysis, DACO: M2.10.2 CBI |
| 1644605 | 2008, Certificates of Analysis, DACO: M2.10.2 CBI |
| 1644619 | DACO: 0.0 |
| 1754564 | 2009, Reply to DACO M2.7.1i additional information request, DACO: 0.8.26 |
| 1754565 | 2004, Vegetative compatibility groups in indigenous and mass-released strains of the entomopathogenic fungus *Beauveria bassiana*: likelihood of recombination in the field, DACO: M2.10.1 |
| 1754566 | 2009, ARSEF listing of *Beauveria bassiana*, HF23, DACO: M2.10.1 |
| 1754569 | 2009, Reply to Screening Deficiency of March 5, 2009 re: DACO M2.10.2, DACO: 0.8.24 |
| 1754570 | 2009, Clarification Responses to DACOM2.10.2, DACO: M2.10.2 CBI |

1754571 2008, 5-lot analysis CoA No. RES-325/3468 Page 1 of 2, DACO: M2.10.2 CBI

1754572 2008, 5-lot analysis CoA No. RES-325/3468 Page 2, DACO: M2.10.2 CBI

1780143 2009, DACO: 0.8 Correspondence with the applicant

## B. Additional Information Considered

### i) Published Information

#### 1.0 Chemistry

1703241 Castrillo LA et. al, Strain-specific detection of introduced *Beauveria bassiana* in agricultural fields by use of sequence-characterized amplified region markers, Journal of Invertebrate Pathology 82, DACO: M2.7.1

1708138 Bidochka, M.J., McDonald, M.A., St. Leger, R.J., Roberts, D.W., 1992, Differentiation of species and strains of entomopathogenic fungi by random amplification of polymorphic DNA (RAPD), Springer Berlin/Heidelberg, Vol. 25, Number 2/February 1994, DACO: M2